REMARKS

This responds to the Non-Final Office Action dated October 22, 2008 (hereinafter "Office Action"). Claims 11, 13-19 and 21-36 are currently amended and fully supported by the above-identified application as filed, such as at [0005]-[0007], [0012]-[0013], [0016], [0017], [0020], [0023], [0024], original claims 11-12, and FIG. 1. Claims 37-44 are new and fully supported by the above-identified application as filed, such as at [0018], [0020] and [0023]. Claims 1-10, 12 and 20 are currently or were previously cancelled without prejudice or disclaimer. Accordingly, claims 11, 13-19 and 21-44 are currently pending and responded to below.

Applicant hereby respectfully requests further examination and reconsideration of this application in view of the foregoing claim amendments and following remarks.

Request for Telephonic Interview

1. If the present amendments and remarks do not result in allowance of all claims, Applicant kindly requests a telephonic interview between the Examiner and Applicant's representative, Gregory Smock, to help expedite examination. As noted below, Applicant's representative can be reached by telephone at (612) 373-6956.

§112 Rejection of the Claims

2. Claims 11, 12, 15, 17, 20-22, 29-31, 33 and 34 were rejected under 35 U.S.C. § 112, first paragraph, as lacking adequate description. Applicant respectfully requests reversal of this rejection based on the claims, as amended.

According to the CCPA, drawings alone or in combination with specification text may provide an adequate written description of an invention. *See In re Wolfensperger*, 302 F.2d 950, 133 USPQ 537 (CCPA 1962). For example, the has CCPA stated:

> The practical, legitimate inquiry in each case of this kind is what the drawing in fact discloses to one skilled in the art. Whatever it does disclose may be added to the specification in words without violation of the statute and rule which prohibit "new matter," 35 U.S.C. 132, Rule 118, for the simple reason that what is originally disclosed cannot be "new matter" within the meaning of this law. If the drawing, then, contains the necessary disclosure, it can "form the basis of a valid claim."

Id. at 542 (emphasis in original).

Claims 11, 12, 15, 17, 20-22, 29-31, 33 and 34:

Claims 11, 15, 17, 21, 22, 29 and 31 have been amended to recite an ocular implant comprising an active agent delivered to tissue via "an exterior surface portion of the implant body," rather than "an exposed medication discharging supply." An example of support for this amendment can be found at least at [0006]-[0007], [0016]-[0017][1], and FIG. 1, such as element numerals 16 and 18, of the above-identified application as filed.

Reconsideration and withdrawal of this basis of rejection is respectfully requested.

3. Claims 22, 30, 31, 33 and 34 were rejected under 35 U.S.C. § 112, first paragraph, as lacking adequate description. Applicant respectfully requests reversal of this rejection based on the claims, as amended.

Claims 22, 30, 31, 33 and 34:

Claims 22 and 38 have been amended to recite an ocular implant comprising an active agent delivered on a sustained release basis to tissue for a "time period between 3–6 months after implant," rather than a "time period of at least about 3 months after implant." An example of support for this amendment can be found at least at [0020] of the above-identified application as filed.

Reconsideration and withdrawal of this basis of rejection is respectfully requested.

4. Claims 11, 12, 15, 17, 20-22, 29-31, 33 and 34 were rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness. Applicant respectfully requests reversal of this rejection based on the claims, as amended.

Claims 11, 12, 15, 17, 20-22, 29-31, 33 and 34:

Claims 11, 15, 17, 21, 22, 29-31, 33 and 34 have been amended to recite an ocular implant extending from a proximal end portion, "configured to seat at or near the lacrimal punctum when implanted," to a distal end portion, "configured for insertion through the lacrimal

[1] The application as filed recites that for a hollow implant, an active agent can be applied to an "interior" surface of the implant, it follows that an "exterior" surface is that surface adjacent the implant's perimeter away from the interior.

punctum into the lacrimal canaliculus when implanted." An example of support for this amendment can be found at least at [0012]-[0013] and FIG. 1.

Reconsideration and withdrawal of this basis of rejection is respectfully requested.

5. Claims 22 and 30 were rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness. Applicant respectfully requests reversal of this rejection based on the claims, as amended.

Claims 22 and 30:

As stated above, claims 22 and 38 have been amended to recite an ocular implant comprising an active agent delivered to tissue on a sustained release basis for a "time period between 3–6 months after implant," rather than a "time period of at least about 3 months after implant." An example of support for this amendment can be found at least at [0020] of the above-identified application as filed.

Reconsideration and withdrawal of this basis of rejection is respectfully requested.

§102 Rejection of the Claims

6. Claims 11, 12, 15, 17, 20-22, 29-31, 33 and 34 were rejected under 35 U.S.C. § 102(b) for assertedly being anticipated by Freeman (U.S. Patent No. 3,949,750).

According to the Federal Circuit, "[a]nticipation requires the disclosure in a single prior art reference of each element of the claim under consideration." *W.L. Gore & Assocs. v. Garlock, Inc.*, 721 F.2d 1540, 200 USPQ 303, 313 (Fed. Cir. 1983).

Claim 11:

Claim 11 presently recites an ocular implant comprising, among other things, an implant body including a porous or absorbent material, and an active agent disposed "entirely throughout" the porous or absorbent material included in the implant body. Applicant respectfully submits that Freeman fails to recite each element recited in Applicant's claim 11, and thus, cannot anticipate such claim. Claims 13-19, 21-29 and 37-40 are dependent on claim 11 and are patentable over Freeman for at least the reason stated above, in addition to the elements recited in such dependent claims.

Reconsideration and allowance of claims 11, 13-19, 21-29 and 37-40 are respectfully requested.

Claim 30:

Claim 30 presently recites an ocular implant comprising, among other things, an implant body including a porous or absorbent material incorporating an active agent "from a proximal end portion" to a "distal end portion" of the porous or absorbent material included in the implant body. Applicant respectfully submits that Freeman fails to recite each element recited in Applicant's claim 30, and thus, cannot anticipate such claim. Claims 31-36 and 41-44 are dependent on claim 30 and are patentable over Freeman for at least the reason stated above, in addition to the elements recited in such dependent claims.

Reconsideration and allowance of claims 30-36 and 41-44 are respectfully requested.

7. Claims 11, 12, 15, 17, 21, 22, 29-31 and 33 were rejected under 35 U.S.C. § 102(b) for assertedly being anticipated by Cohan et al. (U.S. Patent No. 6,196,993) (hereinafter "Cohan"). Applicant respectfully requests reversal of this rejection on the ground that Cohan fails to recite each element of the claims, as amended.

According to the Federal Circuit, "[a]nticipation requires the disclosure in a single prior art reference of each element of the claim under consideration." *W.L. Gore & Assocs. v. Garlock, Inc.*, 721 F.2d 1540, 200 USPQ 303, 313 (Fed. Cir. 1983). In addition, the prior art reference must disclose each element of the claimed invention "arranged as in the claim."[2]

Claim 11:

Claim 11 presently recites an ocular implant comprising, among other things, an implant body including a "porous or absorbent material." In contrast, Cohan recites an insert body molded or otherwise formed from a material "that is impermeable to the medication which will fill the reservoir." (Cohan at col. 4, ll. 28-31)(emphasis added.) In fact, the operability of Cohan relies on the insert body being impermeable, such that medication within the interior reservoir is directed out a geometry-controlled collarette pore at the insert's proximal end. For example, Cohan recites:

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[2] *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481 (Fed. Cir. 1984) (citing *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983))(emphasis added).

> The geometry of the pore 42 leading from the reservoir 34 to the lacrimal lake 12 controls the rate of flow, I, of medication from the ophthalmic insert 32.

(Cohan at col. 6, ll. 31-34; *see also* Office Action at p. 6 recognizing "[a] pore in the collarete [sic] allows for the exit of medication.")(emphasis added.)

Furthermore, claim 11 presently recites an active agent disposed "entirely throughout" the porous or absorbent material included in an implant body. In contrast, Cohan—as recognized by the Office Action[3]—discloses a medication reservoir within an interior surface of an insert body. For example, Cohan recites:

> A reservoir is contained at least partially within the body portion and in fluid communication with the pore, wherein the reservoir is designed to store and release medication through the pore.

(Cohan at Abstract; *see also*, col. 2, ll. 40-54, FIGS. 3, 7 and 9)(emphasis added.) Contrary to the interior medication storage of Cohan, Applicant's claimed ocular implant as recited in claim 11 includes an active agent entirely throughout the porous or absorbent material included in the implant body, including its outer periphery portions providing a retentive shape to the implant.

Because Cohan does not recite an ocular implant comprising an active agent disposed "entirely throughout" a porous or absorbent material included in an implant body, nor an implant body including a "porous or absorbent" material, as recited in Applicant's claim 11, Cohan cannot anticipate claim 11. Claims 13-19, 21-29 and 37-40 are dependent on claim 11 and are patentable over Cohan for at least the reasons stated above, in addition to the elements recited in such dependent claims.

Reconsideration and allowance of claims 11, 13-19, 21-29 and 37-40 are respectfully requested.

Claim 24:

Claim 24 presently recites an ocular implant wherein the "exterior surface portion" of the implant body releases the active agent at or near an implant distal end portion, the active agent configured to treat, at least in part, the nasolacrimal system. In contrast, Cohan discloses an insert in which distal medication administration is precluded by an impermeable reservoir configuration. For example, Cohan recites:

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[3] "A pore in the collarete [sic] allows for the exit of medication from the reservoir within the plug body." (Office Action at p. 6)(emphasis added).

> A reservoir is contained at least partially within the body portion and in fluid communication with the pore, wherein the reservoir is designed to store and release medication through [a] pore [in a proximally-positioned collarette].

(Cohan at Abstract; *see also*, col. 2, ll. 40-54, FIGS. 7 and 9)(emphasis added.) Contrary to the proximal pore medication release of Cohan, Applicant's claimed ocular implant as recited in claim 24 can provide active agent release via an exterior surface portion of the implant body at or near the implant's distal end portion.

Reconsideration and allowance of claim 24 and dependent claim 25, if rejoined, are respectfully requested.

Claim 30:

Claim 30 presently recites an ocular implant comprising, among other things, an "implant body including a porous or absorbent material" incorporating an active agent "from a proximal end portion" to a "distal end portion" of the porous or absorbent material included in the implant body. In contrast, as previously discussed, Cohan only discloses storing medication inside a reservoir positioned within an interior surface of an insert body, and furthermore, requires the insert body to be formed of an impermeable, unsaturateable material. (*See* Cohan at Abstract; col. 2, ll. 40-54; col. 6, ll. 31-34; FIGS. 7 and 9.)

Because Cohan does not recite an ocular implant comprising an "implant body including a porous or absorbent material" incorporating an active agent "from a proximal end portion" to a "distal end portion," of the porous or absorbent material as recited in Applicant's claim 30, Cohan cannot anticipate claim 30. Claims 31-36, 38 and 41-44 are dependent on claim 30 and are patentable over Cohan for at least the reasons stated above, in addition to the elements recited in such dependent claims.

Reconsideration and allowance of claims 30-36, 38 and 41-44 are respectfully requested.

§103 Rejection of the Claims

8. Claims 11, 12, 15, 17, 20-22, 29-31, 33 and 34 were rejected under 35 U.S.C. § 103(a) as assertedly being unpatentable over Freeman in view of Bhushan (U.S. Publication No. 2004/0137068). Applicant respectfully requests reversal of this rejection on the ground that there is no *prima facie* case of obviousness for the claims.

According to the Federal Circuit in *In re Lee*, "there must be some motivation, suggestion, or teaching of the desirability of making the specific combination that was made by the applicant." 61 USPQ.2d 1430 (Fed. Cir. 2002). However, such motivation to combine is lacking when the references teach away from the claimed combination. *See Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 443, 230 U.S.P.Q. 416 (Fed. Cir. 1986)(A reference should be considered as a whole, and portions arguing against or teaching away from the claimed invention must be considered.)

Claims 11, 12, 15, 17, 20-22, 29-31, 33 and 34:

While recognizing that Freeman fails to establish all elements recited in Applicant's claims 11, 15, 17, 21, 22, 29-31, 33 and 34, the Office Action asserts that it would have been obvious to look to Bhushan to establish the missing claim elements. (Office Action at pp. 8-9.) Applicant submits, however, that Bhushan actually teaches away from the claimed implant body including a "porous or absorbent, inert material" including an active agent disposed "entirely throughout" or "from a proximal end portion to a distal end portion of" the porous or absorbent material. In contrast to Applicant's claimed combination, Bhushan discloses a medication reservoir within an interior surface of an insert body. For example, Bhushan recites:

> The insert may also be insoluble, in which case the agent is released from an internal reservoir through an outer membrane via diffusion or osmosis.

(Bhushan at [0045]; *see also*[0073].)

Because Bhushan actually expressly teaches away from the claimed combination, this asserted combination of Bhushan and Freeman is improper and fails to establish all elements recited in Applicant's claims.

Reconsideration and allowance of claims 11, 13-19 and 21-44 are respectfully requested.

Reservation of Rights

9. In the interest of clarity and brevity, Applicant may not have equally addressed every assertion made in the Office Action, however, this does not constitute any admission or acquiescence. Applicant reserves all rights not exercised in connection with this response, such as the right to challenge or rebut any tacit or explicit characterization of any reference or of any of the present claims or the right to challenge or rebut any asserted factual or legal basis of any

of the rejections. To the extent that any rejection or assertion is based upon the Examiner's personal knowledge, rather than any objective evidence of record as manifested by a cited prior art reference, Applicant timely objects to such reliance on Official Notice, and reserves all rights to request that the Examiner provide a reference or affidavit in support of such assertion, as required by MPEP § 2144.03. Applicant reserves all rights to pursue any cancelled claims in a subsequent patent application claiming the benefit of priority of the present patent application, and to request rejoinder of any withdrawn claim, as required by MPEP § 821.04.

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited and encouraged to telephone Applicant's representative at (612) 373-6956 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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Date April 22, 2009

By _____
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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on April 22, 2009.

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